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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,767	11/04/2003	Andrew Thomas Forsberg	47563.0009	6326
57600	7590	01/05/2007		
HOLLAND & HART LLP 60 E. SOUTH TEMPLE SUITE 2000 SALT LAKE CITY, UT 84111			EXAMINER POUS, NATALIE R	
			ART UNIT	PAPER NUMBER
			3731	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/05/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/700,767	<b>Applicant(s)</b> FORSBERG ET AL.	
	<b>Examiner</b> Natalie Pous	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 October 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 and 42-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 42-53 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/16/06, 3/4/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

#### **Regarding the Abstract**

Examiner acknowledges amendment to the abstract, thus the previous objection to the abstract is withdrawn

#### **Regarding Bogert**

Applicant's arguments, see page 9 filed 10/26/06, with respect to Dodge have been fully considered and are persuasive. The 102 rejection of claim 1 with respect to Dodge has been withdrawn.

#### **Regarding the combination of Kensey and Bogart**

Applicant's arguments filed 10/26/06 have been fully considered but they are not persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would be desirable to provide an introducer sheath that can easily penetrate tissue. The combination of Kensey and Bogart provides this advantage by combining an introducer sheath for penetrating the body (Kensey) and a device for easily penetrating tissue (Bogart), thus there is motivation to combine the references.

Regarding applicants arguments that the "sharpened tip" of Bogart teaches away from modifying the introducer sheath, examiner notes that the feature combined with the

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introducer sheath is the composite structure of Bogart which provides stiffness and rigidity to the end of the device, not the "sharpened tip," thus applicants remarks with respect to this feature are moot. Thus, examiner sustains the previous 103 rejections with respect to the combination of Kensey and Bogart.

**Regarding the combination of Kensey and Buck**

Applicant's arguments filed 10/26/06 have been fully considered but they are not persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would be desirable to provide an introducer sheath that effectively guides the sealing plug from the introducer sheath. The combination of Kensey and Buck provides this advantage by combining an introducer sheath for penetrating the body (Kensey) and a device for guiding the sealing plug (Buck), thus there is motivation to combine the references.

Regarding applicants arguments that the "tip having two openings" of Bogart teaches away from modifying the introducer sheath, examiner notes that the feature combined with the introducer sheath is the curved structure of Buck which aids in guiding the plug from the sheath, not the "tip having two openings," thus applicants

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remarks with respect to this feature are moot. Thus, examiner sustains the previous 103 rejections with respect to the combination of Kensey and Buck.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 4, 5, 13, 42, 45 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kensey et al. (US 5861004) in view of Bogert et al. (US 6096012).

Kensey teaches a puncture closure assembly, comprising the following:

- a tissue puncture closure device (22) having a distal and a proximal end
- a vascular insertion sheath (28) wherein the distal end of the insertion sheath (28c) comprises a tip portion
- a filament (34) extending from the proximal end of the closure device to the distal end of the closure device

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- an anchor (32) for insertion through a tissue wall puncher attached to the filament at the distal end of the closure device (fig. 1)
- a sealing plug (30) slidably disposed about the filament at the distal end of the closure device (fig. 1).
- A hemostatic valve (28a) coupled to the proximal end of the tubular member (fig. 13)

Kensey fails to disclose the following:

- wherein the tip portion is stiffer than the insertion sheath portions adjacent to the tip portion
- wherein the stiffer tip portion comprises a second layer of material wherein the wall thickness is greater at the tip portion than at the portion adjacent to the tip portion

Bogart teaches an insertion sheath wherein the distal tip portion is stiffer than the insertion sheath portions adjacent to the tip portion wherein the stiffer tip portion comprises a second layer of material making the tip portion thicker than the rest of the sheath in order to enable insertion into the body of the patient (Column 3, proximate lines 30-48). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kensey with a stiffer tip portion as taught by Bogart in order to enable insertion of the sheath into the body of the patient.

Claims 1, 2, 3, 8, 9, 13, 14, 17, 18, 42-44, 49, 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kensey et al. (US 5861004) in view of Buck et al. (US 6270470).

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Kensey teaches a puncture closure assembly, comprising the following:

- a tissue puncture closure device (22) having a distal and a proximal end
- a vascular insertion sheath (28) wherein the distal end of the insertion sheath (28c) comprises a tip portion
- a filament (34) extending from the proximal end of the closure device to the distal end of the closure device
- an anchor (32) for insertion through a tissue wall puncher attached to the filament at the distal end of the closure device (fig. 1)
- a sealing plug (30) slidingly disposed about the filament at the distal end of the closure device (fig. 1).
- A hemostatic valve (28a) coupled to the proximal end of the tubular member (fig. 13)

Kensey fails to disclose the following:

- wherein the tip portion is stiffer than the insertion sheath portions adjacent to the tip portion
- wherein the stiffer tip portion comprises a concave fold
- wherein the concave fold comprises no more than half of a circumference of the insertion sheath
- the stiffer tip portion comprises at least one stiffening ridge
- the stiffer tip portion comprises at least 2 stiffening ridges
- at least a portion of the fold comprises a thicker wall at the edge of the fold than the flexible tubular member

Buck teaches in insertion sheath (22) wherein the tip portion (24) is stiffer than the insertion sheath portions adjacent to the tip portion wherein the stiffer tip portion comprises a concave fold (fig. 7), wherein the concave fold is comprises no more than half of a circumference of the insertion sheath (fig. 6a), the stiffer tip portion comprises at least one stiffening ridge (32), the stiffer tip portion comprises at least 2 stiffening ridges (30, fig. 10), at least a portion of the fold comprises a thicker wall than the flexible tubular member (32) at the edge of the fold (fig. 4) in order to guide the sealing plug out of the sheath and into the body. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Kensey with areas of increased stiffness as taught by Buck in order to guide the sealing plug out of the sheath and into the body.

Claims 5-7, 15-16, 47,48 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Kensey and Buck as applied to claim 1 above, and further in view of Bogart. The combination of Kensey and Buck teaches all limitations of preceding dependent claim 1 and further teaches a concave fold along the tip portion. The combination of Kensey and Buck fails to disclose wherein a second layer of material is disposed along the edge of the concave fold. Bogart teaches a vascular insertion sheath comprising a second layer of material (28) disposed along the edge of the tip of the sheath in order to in order to enable insertion into the body of the patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Kensey and Buck with a second layer of material as taught by Bogart in order to enable insertion into the body of the patient.



Claims 10-12, 19-21 and 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Kensey and Buck as applied to claims 1, 14 and 42 above, and further as a matter of design choice. Since the applicant has not disclosed that providing orthogonal ridges or a transverse corrugated section provides any advantage over longitudinal ridges, and it appears that the combination of Kensey and Buck performs the task of guiding the sealing device out of the sheath and inhibiting re-entry of the device equally well as that disclosed in the application, it would have been an obvious matter of design choice to modify the combination of Kensey and Buck with transverse ridges or corrugations.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP  
12/12/06

  
ANH TUAN T. NGUYEN  
SUPERVISORY PATENT EXAMINER

12/22/06